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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/593,940	09/22/2006	Carl Ekholm	1876.017US1	5408

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EXAMINER
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YARNALL, MEGAN LEIGH

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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12/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/593,940

Applicant(s)

EKHOLM ET AL.

Examiner

Megan Yarnall

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 September 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>092206</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claim 2 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 2 refers to a third hole for attaching a third tubercle, however, there are only two tubercles, the greater and lesser tubercles, on the humerus. Therefore, it is unclear as to how one skilled in the art could make and/or use the invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 5 recites the limitation "the neck of the prosthesis" in lines 2 and 3 and "the trial prosthesis" in lines 5 and 6. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 6 recites the limitation "the targeting arm" in line 3. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 7 recites the limitation "the targeting arm" in line 2. There is insufficient antecedent basis for this limitation in the claim.

8. Note that in view of the indefinite nature of the above claims, the claims have been examined as best understood.

***Claim Rejections - 35 USC § 101***

9. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 9 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claim 9 positively claims an anatomical part, the humeral shaft, in line 4, which is regarded as non-statutory subject matter.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-4, and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Masini 2002/0151982. Masini discloses a shoulder prosthesis including a stem, a neck, and a head (par.24, ll.10-12), wherein the neck is provided with lateral and anterior holes for anchoring screws 410 to attach greater and lesser tubercles (fig.4; par.7, ll.12-15; clms. 17, 18), further comprising a third hole in the neck for a posterior anchoring screw (fig. 2A; par.7, ll.7-10), wherein the top end of the prosthetic stem is tapered 530

(fig.5), wherein a lateral 202 and anterior fin project from the neck of the prosthesis, the lateral fin having a shorter length than the anterior fin and the anterior fin angled to point to at the bicipital groove (fig.2A), and wherein a further hole is provided in the neck capable of receiving an attachment part of a targeting arm (fig.2A).

12. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Behrens 5,334,192. Behrens discloses targeting arm 9 attachable to a neck of a prosthesis (col.3, ll.40-42) with guide means 10-13 for guiding anchoring screws 26 into the neck, wherein guide means 10-13 are capable of guiding screws into a lateral hole and an anterior hole in the neck, and wherein targeting arm 9 is capable of holding a prosthesis (fig.3).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Masini 2002/0151982 in view of Behrens 5,334,192. Masini discloses the invention substantially as claimed. However, Masini does not disclose that a targeting arm is stabilized by engaging a peg into a hole of an anterior fin.

15. Behrens teaches a targeting arm comprising plug 3 with nose 4, in the analogous art of femoral nails, to accommodate a corresponding recess in a femur nail to attach and secure the implant (col.3, ll.40-42).

16. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the prosthesis of Masini to include the targeting arm with the attachment mechanism of Behrens to attach and secure the implant as taught by Behrens, col.3, ll.40-42.

17. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Behrens 5,334,192 in view of Johnstone 2005/0177175. Behrens discloses the invention substantially as claimed. However, Behrens does not disclose the use of a guide wire for guiding a screw into place in a hole in a prosthesis.

18. Johnstone teaches a jig with guide wires, in the same field of endeavor, for the purpose of inserting screws to secure the prosthesis (par.40).

19. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to add the guide wires taught by Johnstone to the targeting arm of Behrens in order to guide the insertion of the screws to secure the prosthesis as taught by Johnstone, par.40. Note that the method of inserting the screw is not germane to the issue of patentability of the device itself and therefore is not given patentable weight.

20. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Behrens 5,334,192 in view of Masini 2002/0095217. Behrens discloses the invention substantially as claimed. However, Behrens does not disclose a trial stem provided with marks for determining the depth of the stem in the canal of the humerus comprising a locking ring surrounding the trial stem, locking the stem to a chosen depth.

21. Masini teaches a prosthesis (par.20, ll.7-9), in the same field of endeavor, provided with a series of score marks to indicate the depth of the prosthesis (clm.25) wherein gasket 334 surrounds the stem to retain the device in place (par.22, ll.3-9).

22. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the prosthesis disclosed by Behrens to include the marks and locking ring taught by Masini in order to determine the depth of the prosthesis as well as hold the prosthesis in place as taught by Masini, clm.25, and par.22, ll.3-9.

### ***Drawings***

23. The drawings are objected to because figure 5 is unclear. It is unclear what the unlabeled shaded regions are showing. The Examiner recommends these regions either be removed or labeled appropriately. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the

changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

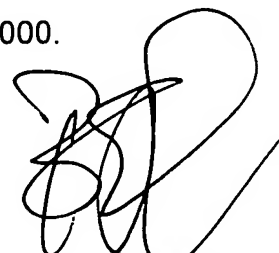
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Megan Yarnall whose telephone number is 571-270-3071. The examiner can normally be reached on Monday-Friday 7:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
12/10/02

  
**BRUCE SNOW**  
PRIMARY EXAMINER